

Supplemental Amendment for Application No. 09/623,068. Applicant(s) MCGINNIS ET AL. 6/10
July 20, 2004 submitted by fax to 1-703-872-9306

Remarks

Regarding new paragraphs that are requested to be added to the Specification

The new paragraph requested to be added to the Background makes use of subject matter and concepts already in the application. Specifically for example, subject matter is from p. 38 lines 21 to 24, p. 8 lines 1 to 3, p. 26 lines 23 to 27, p. 13 lines 20 to 25, p. 44 lines 20 to 22 and p. 45 lines 14 to 20 of the PCT application. Regarding the elimination of the Summary section from the Background in the recent Amendment of 6/29/04, the applicants respectfully submit that a Summary of the Invention section is not a requirement

The other new six paragraphs requested to be added to the specification consist mainly of subject matter from the inventor's paper Annals of Human Genetics, 1998, vol. 62, pp. 159-179, abbreviated as AHG 98 herein. Specifically for example, subject matter is from information on χ^2_{tdt} in Tables 1, 2 and 3 from p. 164, from the Abstract on p. 159, the definitions of χ^2_{tdt} , n_a , n_b , and n_{tdt} from p. 161, information on the power calculations using the binomial distribution on page 164, information on singletons from pages 168 and 169, information on the Risch & Merikangas analysis from pages 168 to 171. Other subject matter regarding the inventor's generalization of the well-known Risch & Merikangas analysis is from the patent application (specifically pp. 5 and 6 of the PCT application) and the inventor's paper AHG 98 (specifically pp. 159 (Abstract), 166, 168 to 171).

Regarding amendments to the Specification and Claims in the recently submitted Amendment/Response of 6/29/04

That Amendment/Response of 6/29/04 was completely responsive the Examiner's Office Action. The applicants, however, respectfully offer some more information that applicants respectfully submit will further put the application in condition for allowance.

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Requested amendments to the claims in the recently submitted Amendment/Response of 6/29/04

Regarding point 2. A) and claim 102. Extensive arguments and evidence of patentability for newly amended claim 102 was presented in the recently submitted Amendment/Response of 6/29/04. The applicants also respectfully offer the following additional information. In general the a) means of the claim includes oligonucleotides that are used as PCR primers or oligonucleotides that are used other than as (or in addition to) PCR primers. Applicants wish to also respectfully point out that latitude is allowed in identifying means of claims with specific apparatus components. More specifically: *"The term 'means' may ordinarily properly include more than one specific detail. Most machine elements or submechanisms properly termed 'means' may be divided up into several parts depending on how specific or to what extent the division is carried"* (from Ex parte Freiburg 49 USPQ 213, 214).

An apparatus component may be two different means. If a submechanism really performs independent functions, there is no objection to including it twice in a claim under each separate function (Ex parte Olsson 65 USPQ 52, 54; see also In re Knowlton 178 USPQ 486, 494 and In re Kelley 134 USPQ 397). And an apparatus claim that includes elements recited in means-plus-function language is adequately supported if the apparatus is adequately described (In re Knowlton 178 USPQ 486, 494). In addition, the term "means" may be used in either a singular or plural sense; there is no limit to the degree of plurality for the term (see Ex parte Anderson, 52 USPQ 552, 555). As the Board stated in Ex parte Anderson: *"if an attempt were made in machines of the complicated character to define the various elements and their relationships by separate expressions, the lengths of the resulting claims would render them extremely confusing, to say the least"*.

Some remarks below regarding the claims are generally made for the record.

Regarding currently amended claim 3. It is clear that it is possible for a particular practice of the claimed process to identify zero or more markers as being linked to the trait-causing polymorphism.

Regarding original claim 78. Claim 78 contains the words "substantially complementary". Given the definition of an oligonucleotide that is "complementary" (p. 20 line 4 of the PCT application), the term "complementary" in this definition is essentially the same as "substantially complementary". And the applicants respectfully submit that the word "substantially" in "substantially complementary" of claim 78 is redundant. And the single word "complementary" means the same thing as "substantially complementary" in this context of claim 78. The applicants respectfully request that the claim be examined on this basis, and respectfully submit that a change from "substantially complementary" to "complementary" in claim 78 is a formality and does not change claim scope.

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Regarding currently amended claim 103 and similar claims. Some claims such as claim 103 contain the phrase "wherein an essentially one-dimensional panel of markers for an association-based study is not chosen" or similar such phrase. Such a phrase is meant to be interpreted in context: the claimed invention is directed to a process for identifying markers linked to a trait-causing polymorphism using chosen covering markers. Each marker chosen in the course of practicing a process as in claim 103 is chosen to be used to identify one or more markers linked to a trait-causing polymorphism.

Regarding currently amended claim 107 and similar claims. Some claims such as claim 107 contain the phrase "wherein a panel of b-allelic markers favoring markers with least common allele frequencies near 0.5 is not chosen". As is clear from the application (p. 22 lines 1 to 5), it is possible for each of one or more multi-allelic markers to be a BME and to be included in a panel of bi-allelic markers.

Regarding claim 118 and similar claims. As noted in the recently submitted amendment/response of 6/29/04, some claims contain the limitation "thousands of covering markers". This limitation is supported by p. 47 line 5 of the PCT application which describes physical implementation and genotyping techniques used by versions of the invention.

Regarding currently amended claim 145 and similar claims. Some claims such as claim 145 contain the phrase "wherein an essentially one-dimensional panel of markers for an association-based study is not chosen" or similar such phrase. Such a phrase is meant to be interpreted in context: the claimed invention is directed to a process for obtaining genotype data/sample allele frequency data. Each marker chosen in the course of practicing a process as in claim 145 has the characteristic in (1): (1) any one chosen marker is chosen so that genotype data/sample allele frequency data is obtained at the marker.

Regarding new claim 160. Applicants respectfully submit that the term "whereby" in the phrase "*whereby each point in the GL-F region has the characteristic described in (1)*" is equivalent to the term "wherein" as the phrase accompanying the term "whereby" in this claim is a positive limitation of the claim. Applicants respectfully request that the claim be examined on this basis. And a change of this term in this claim from "whereby" to "wherein" is a formality and does not change the scope of the claim. (A whereby clause that sets forth a structural limitation and not merely the results achieved by the claimed structure is a positive limitation of the claim; see *Scheinman vs. Zalkind* 46 USPQ 141, 143).

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Regarding currently amended claim 166. Claim 166 contains the phrase "wherein an essentially one-dimensional panel of markers for a linkage study is not chosen". Such a phrase is meant to be interpreted in context. The claimed invention is directed to one or more copies of a set of oligonucleotides that is complementary to a chosen group of covering markers.

Regarding new claim 167. This new claim has a minor error or informality. The claim has the words "so that" struck out and the next word "whereby" underlined as if the claim is currently amended rather than new. As is obvious, the words "so that" should not appear at all; and the word "whereby" should not be underlined.

A requested amendment to the Specification in the recently submitted Amendment/Response of 6/29/04 The term "unidentified" requested to be added to the Background on page 24 of the Amendment/Response of 6/29/04 is from p. 44 line 15 of the PCT application.

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Conclusion

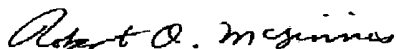
Twenty claims (3 independent, 17 singly dependent) have been favorably examined and allowed in a previous Office Action. These are claims 3-5, 8, 20, 21, 33-35, 38, 50, 51, 78-80, 83, 95 and previously added claims 99-101.

The recently submitted amendment/response of June 29, 2004 was fully responsive to the Examiner's Office Action. Previously allowed claim 3 was slightly amended in the recently submitted amendment/response of June 29, 2004. Extensive amendments to most of previously added claims 102 to 159 were also made in the recently submitted amendment/response of June 29, 2004. However all of these claims are still based on the new two-dimensional CL-F approach. And 12 new claims 160 to 171 were added in the recently submitted amendment/response of June 29, 2004. New arguments and evidence of patentability for amended claim 102 were respectfully submitted on June 29, 2004. And extensive amendments to the specification and abstract were respectfully submitted on June 29, 2004 as well.

In the present supplemental amendment some further arguments regarding the patentability of claim 102 are also respectfully submitted. And in the present supplemental amendment the applicants also respectfully request further amendments to the specification. These additions are specifically one new paragraph to the Background and six new paragraphs to the Description. For the record, some further remarks with respect to the claims are made.

For the reasons advanced above, applicants respectfully submit that the application is now in condition for allowance and that action is earnestly solicited. Applicants again express thanks to the Examiner for his observations and comments in the previous Office Actions.

Respectfully submitted,



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